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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/080,127	05/15/1998	ALEXANDER BLINKOVSKY	5253.200-US	9075

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NOVOZYMES BIOTECH, INC.
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EXAMINER

TURNER, SHARON L

ART UNIT	PAPER NUMBER
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1647

DATE MAILED: 08/12/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/080,127

Applicant(s)

BLINKOVSKY ET AL.

Examiner

Sharon L. Turner

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 28 May 2003.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 207-236 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 207-221 is/are allowed.
- 6) ☒ Claim(s) 222-236 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: |

Response to Amendment

1. The amendment filed 5-28-03 has been entered into the record and has been fully considered. Claims 237-240 are canceled. Claims 207-236 are pending.
2. The text of Title 35 of the U.S. Code not reiterated herein can be found in the previous office action.
3. As a result of Applicant's amendment, all rejections not reiterated herein have been withdrawn by the Examiner.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 222-236 are rejected under 35 U.S.C. 102(b) as being anticipated by Kundu et al., Applied Microbiology, April 1970, p. 598-603.

Claim 222 is directed to a method for producing the polypeptide of claim 207 comprising cultivating a microbial strain, which in its wild type form produces the polypeptide in a medium and under conditions suitable for the production of the polypeptide and recovering the polypeptide from the medium. Kundu teach cultivation of *Aspergillus oryzae* that is disclosed as the wild type organism producing the peptide of claim 207. The culture conditions are inherently effective for the production of the

polypeptide as the conditions are suitable for the growth and propagation of the organism. Thus, the growth conditions are considered to be a medium and under conditions suitable for the production of the polypeptide produced by the organism, absent convincing factual evidence to the contrary. The polypeptide is considered to be suitably produced and recovered from the media in that the reference teaches the preparation of culture protein isolates from broth obtained by submerged fermentation, see in particular Materials and Methods, pp. 598, columns 1-2. The peptide is thus obtained (recovered) from the culture isolates. However, the peptide is not deemed to be "isolated" as in claims 207-221 in that the recovered peptides are from the cellular preparation and thus would not be "essentially free of other non-aminopeptidase proteins" as defined in the specification at p. 9, lines 6-7. Claims 223-236 are drawn to compositions comprising the peptide of claim 207. However, the compositions "comprise" the protein and thus are not "isolated" as in claim 207. The compositions further comprise a suitable carrier in addition to the peptide of claim 207. The composition of Kundu is deemed to comprise the peptide of claim 207 in that the preparation of Kundu is whole *Aspergillus oryzae* protein preparations obtained from the same wild-type organism as noted in claim 207. Thus the Kundu composition is deemed to inherently comprise the claimed peptide absent evidence to the contrary. In that the composition is deemed limited only to the extent of a product by process claim, whereby the composition is created by the addition of a suitable carrier, a composition which shares the same peptide and a suitable carrier would meet the limitations. Indeed the composition "comprising" is not necessarily "isolated" as in claim 207.

Kundu teaches the preparation wherein the fermentation cultures are in media and/or distilled water following ethanol precipitation, see for example p. 598 columns 1-2, Materials and Methods. Both the media and water are suitable carriers. Thus, the reference teachings anticipate the claimed invention directed to the method of producing the polypeptide and a composition comprising it and a suitable carrier.

Applicant's argue in the response of 5-28-03 that Kundu et al does not disclose every element of the invention claimed, in particular the production of a secreted polypeptide having amino peptidase activity as claimed.

Applicant's arguments filed 5-28-03 have been fully considered but are not persuasive. Applicant's claims are drawn to a method of producing the secreted polypeptide of claim 207 comprising cultivating a microbial strain, which in its wild-type form produces the polypeptide in a medium under conditions suitable for production of the polypeptide; and recovering the polypeptide from the medium. It is noted that the peptide of claim 207 is in isolated form. As defined in the specification at p. 9, lines 6-7 isolated form is essentially free of other non-aminopeptidase polypeptides. Yet the method as defined in claim 222 fails to delineate those method steps which would result in the claimed peptides isolation free of other non-aminopeptidase polypeptides. Even though the claim references the peptide of claim 207 the peptide as claimed in claim 222 is not noted to be in isolated form and no steps provide for it in the absence of other non-aminopeptidase polypeptides. Thus, the Examiner may rely on inherency in that the *Aspergillus oryzae* culture would be expected to produce the peptide of claim 207 in it's natural form as the strain is the preferred of Applicant's invention and is in its wild-

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type capable of producing the peptide when cultured as noted. Kundu provides the isolated medium via the isolation of cultured protein isolates from submerged fermentation broth. The courts have settled that a product inherently possesses all characteristics of that product (see, e.g., *Ex parte Gray*, 10 USPQ2d, 1922; *In re Best*, 195 USPQ 430), and that "the PTO can require an applicant to prove that the prior art products do not necessarily or inherently possess the characteristics of his claimed product. Further, it is well noted that process limitations cannot distinguish a claimed product. Accordingly, since the issue is whether the protein preparation of the prior art from *Aspergillus oryzae* is patently indistinct from that of the claimed material, Appellants have the burden of showing that inherency is not involved". *Ex parte Gray*, 10 USPQ 2d 1922 (1989); *In re Best*, 195 USPQ 430 (CCPA 1976). While the peptide of claim 207 is "isolated" the peptide produced via the claimed method and in composition is not so isolated and thus the prior art reference to the method of isolation and composition are sufficient to meet all limitations of the claimed invention. Suitable evidence to the contrary would require showing that the Kundu organism and/or preparation did not produce or contain a peptide with the characteristics of claim 207.

Status of Claims

6. Claims 207-221 are allowed. Claims 222-236 are rejected. Claims 237-240 are canceled.

Conclusion

GARY KUNZ
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600

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7. Any inquiry of a general nature or relating to the status of this general application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Papers relating to this application may be submitted to Technology Center 1600, Group 1640 by facsimile transmission. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). Should applicant wish to FAX a response, the current FAX number for Group 1600 is (703) 308-4242.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sharon L. Turner, Ph.D. whose telephone number is (703) 308-0056. The examiner can normally be reached on Monday-Friday from 8:00 AM to 4:30 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz can be reached at (703) 308-4623.

Sharon L. Turner, Ph.D.
July 29, 2003


GARY KUNZ
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600